REMARKS

SPECIFICATION

Applicant's attorney notes the reference to the preferred layout and content of the specification. Since this layout and content was used throughout the application (which was retyped from the parent application), applicant does not understand the reason for this page of the action.

The references listed on pages 5-7 are footnotes to the preceding section. This arrangement is widely used, and in fact is the arrangement of the patent issued on the parent application, U.S. Patent 6,306,391. Should the Examiner persist in this requirement and should all other grounds of objection and rejection be deemed overcome, the Examiner is hereby authorized to move these references by Examiner's amendment.

CLAIM REJECTIONS - 35 U.S.C. § 112

Claim 22 was rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, with respect to "betalactams" and "quinolones."

The specification contains numerous examples of betalactams, including the penicillins and cephalosporins listed in the first full paragraph of page 3, the examples on pages 10-12, and the first paragraph of page 23 would all be recognized by those skilled in the art as examples of betalactams. This recognition is emphasized by the references cited, such as reference 5 ("Betalactam therapy and intestinal flora") and reference 16 ("Prevention of beta-lactam-associated diarrhea by saccharomyces boulardii compared with placebo"). The

term "quinolones" has been replaced with the term "fluoroquinolones" which finds support in the specification at page 3, line 14.

Claims 1-18 and 22-24 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention. The grounds are discussed below.

"In claim 1, it is not clear if both the first and second ingredient could be coated." Claim 1 says "at least one of the first and second active ingredients being coated," and claim 7 sets out that both may be coated.

"What is the 'active ingredient' referring to on line 6 of claim 1? Which active ingredient?" The claim is believed to be clear that either active ingredient, or both, could be coated.

"How could the active ingredients be contained in a single formulation if the form was a powder, how then could they be separated by a protective barrier? The markush groups are confusing since they provide combinations which do not necessarily produce compositions which would make compositions as claimed." The claim says that the "single formulation" is "selected from the group consisting of a powder, a tablet, and a capsule." The production of a powder in which one of the active ingredients is coated is described in Example IV at page 21 of the specification. In the process, one of the active ingredients is granulated after suspending it in a coating suspension by a process known to those skilled in the art. The granules so prepared are dried and mixed with a dry powder containing another active ingredient by processes known to those skilled in the art. Thus, at least some of the granules of the powder are coated to protect them from other granules of the powder.

"In claim 15, it is not clear in line 5, what the tablet is physically separated by." Claim 15 is drawn to a composite tablet such as the one disclosed in Example II (iv) at page 13. In such a tablet, rather than coating granules of the anti-infective agent or granules of the microorganism, the two active ingredients are physically separated as by keeping all of one ingredient in one layer and all of the other ingredient in another layer, or by forming a tablet of one ingredient with a hole in it and filling the hole with the other ingredient. As set out at page 13, lines20-22, "Coating/barrier protection is not so much necessary as it is in a capsule form as long as moisture content is controlled and physical separation is maintained in a same tablet." The physical separation is thus spatial, and not necessarily by an intervening coating.

but something is still holding them in place

"In claim 16, it is not clear which 'active ingredient' the protective barrier is to go around." Claim 16 has been amended to make clear that the protective coating goes around whichever active ingredient is "in said at least one layer."

no antecedent basis!

CLAIM REJECTIONS - 35 U.S.C. § 102

Claims 1, 3, 6-8, 15-18 and 22-24 have been rejected under 35 U.S.C. § 102(b) as being anticipated by FR 6855. This rejection is respectfully traversed.

The claims are directed to a formulation which includes an anti-infective agent and a microorganism which is "**susceptible to said anti-infective agent.**" FR 6855 utilizes a mixture of tetracycline and bacteria. As is well known in the art, tetracycline is a bacteriostatic drug, rather than a bacteriocidal. Because the bacteria in the formulation are not actively growing, there is no reason to believe that tetracycline would have any effect on the organisms in the formulation. Therefore, because of the formulation described in FR 6855, neither the problem addressed by the present invention nor its solution is shown or suggested by this reference.

So what? and where is this evidence?

really? where is evidence of this.

Further, FR 6855 teaches that the lactic ferment must be generally resistant to antibiotics administered orally in massive doses. This use of resistant microorganisms is avoided by the present invention.

Claim 1 has also been rejected under 35 U.S.C. § 102(b) as being anticipated by FR 5247. This rejection is respectfully traversed.

Published application FR 5247 also relates to a combined formulation in which the antibiotic is tetracycline. Again, tetracycline is a bacteriostatic drug, rather than a bacteriocidal, and because the bacteria in the formulation are not actively growing, there is no reason to believe that tetracycline would have any effect on the organisms in the formulation. Therefore, because of the formulation described in FR 5247, neither the problem addressed by the present invention nor its solution is shown or suggested by this reference. As noted above, the claims are directed to a stable formulation which includes an anti-infective agent and a microorganism which is "susceptible to said anti-infective agent."

It should be noted that FR 5247 also suggests using resistant organisms and suggests that their resistance may disappear. It therefore cannot either disclose or suggest the formulation of the present invention, which avoids the use of resistant organisms.

CLAIM REJECTIONS - 35 U.S.C. § 103

Claims 1-18 and 22-24 have been rejected under 35 U.S.C. § 103(a) as being obvious over FR 5247 in view of FR 6855 and further in view of Black et al. The same claims have been rejected as obvious over FR 6855 in view of Black et al. These rejections are respectfully traversed.

Black et al. teaches administering ampicillin and microorganisms in separate formulations at separate times.

None of the references suggests combining an anti-infective with a micro-organism which is susceptible to the anti-infective in a single formulation. Thus, nothing in the references, alone or combined, suggests the invention as set out in the claims.

The dependent claims set out further non-obvious features of the invention. By way of example, the combinations of claim 2 and 3, in the claimed invention, are not suggested by any of the prior art, alone or in combination. The ratios, the coating of granules, the coating materials, and the physical configurations of the formulations set out in the dependent claims are not suggested by any of the cited art, alone or in combination.

It is therefore respectfully requested that the case be passed to issue.

Should the Examiner not be prepared to allow all of the claims, he is requested to call applicants' undersigned attorney to arrange an interview before issuing a final rejection.

Respectfully submitted,

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